

BACKGROUND¹

In the face of a compelling need for Psychomedics's SOPs, and despite several efforts by Plaintiffs in aid of resolving the issues raised in the Motion, Psychomedics continues to hide behind broad and conclusory objections based on alleged burden and confidentiality. Psychomedics has further sought to escape its obligations under the subpoena by submitting the Thistle Affidavit, attached to Psychomedics's Opposition to the Plaintiffs' Motion to Compel (the "Opposition") as Exhibit C. Mr. Thistle is Senior-Vice President and General Counsel of Psychomedics. Thistle Affidavit at 1. The Thistle Affidavit is the sole support provided by Psychomedics for each of the following propositions: (i) the SOPs in question are non-public, confidential documents that represent the blueprints for Psychomedics' business and that govern its patented methodology for hair testing (Opposition at 3); (ii) information contained in the SOPs is critical to Psychomedics's financial and competitive well-being (*id.* at 3-4); (iii) the production of the SOPs to the Plaintiffs would result in harm to Psychomedics (*id.* at 4); and (iv) the group of scientists practicing hair drug testing is very small, and thus it is highly likely that an opposing expert in the instant action will work for a competitor in the industry at some point (*id.*). The Thistle Affidavit should be stricken from the record because it presents immaterial, impertinent, misleading, and conclusory factual assertions, including factual assertions not within Mr. Thistle's personal knowledge. The Thistle Affidavit should be stricken for the additional reason that it contains a steady series of legal opinions as to matters reserved for this Court.

¹ The background concerning Plaintiffs' subpoena to Psychomedics, defendants' drug test performed on hair samples (the "Hair Test"), and the importance of Psychomedics's Standard Operating Procedures ("SOPs") to the issues presented in this case, is set forth in the Memorandum in Support of Plaintiffs' Motion to Compel Psychomedics to Produce Its SOPs For Testing Hair Samples For Drugs of Abuse ("Plaintiffs' Motion to Compel") filed with the Court on May 15, 2007.

ARGUMENT

I. THE COURT SHOULD STRIKE THE THISTLE AFFIDAVIT BECAUSE IT CONTAINS IMPERMISSIBLE LEGAL OPINIONS.

Affidavits are vehicles for the presentation of *facts*, not legal arguments, to the Court; affidavits that contain either arguments as to facts or conclusions of law are improper. *See, e.g.*, 3 AM. JUR. 2D *Affidavits* § 13 (2007) (“statements in affidavits as to opinion, belief, or conclusions of law are of no effect”); 6 JAMES WM. MOORE ET AL., *MOORE’S FEDERAL PRACTICE* ¶ 56.22(1) (1995) (“[t]he affidavit is no place for ultimate facts and conclusions of law”).² Arguments concerning the facts and the law should be made in briefs. Conclusions of law contained in an affidavit are extraneous and should be stricken or disregarded, and only the facts considered. *Northern Light Technology v. Northern Lights Club*, 97 F.Supp.2d 96 (D. Mass. 2000) (striking portions of an affidavit offering legal arguments and conclusions); *Richardson v. Oldham*, 12 F.3d 1373, 1378 (5th Cir. 1994) (finding that court properly struck one portion of affidavit as not based on personal knowledge and another portion on basis that it asserted legal conclusion); *A.L. Pickens Co., Inc. v. Youngstown Sheet & Tube Co.*, 650 F.2d 118, 121 (6th Cir. 1981) (holding that affiant’s opinion on the ultimate legal question before the court was “not entitled to any weight whatsoever”); *Hardin v. Reliance Trust Co.*, 2006 WL 2850457 at *5 (N.D. Ohio) (granting motion to strike portions of affidavit in which affiant attempted to make legal arguments). Affidavits submitted by attorneys for the parties are tested under these same standards. 11 JAMES WM. MOORE ET AL., *MOORE’S FEDERAL PRACTICE* ¶ 56.14[1][c] (2006).

The Thistle Affidavit should be stricken or disregarded because it states multiple legal arguments and conclusions, including the following: (i) “the plaintiffs’ claim that no proprietary rights reside in Psychomedics [sic] test methods described in publicly available documents (e.g., published studies and patents) misses the mark. . . .” (Thistle Affidavit at 2); (ii) “Psychomedics

² Local Rule 7.1(b)(2) states that an opposition to a motion may be supported by an affidavit “setting forth or evidencing facts on which the opposition is based.” An affidavit that contains arguments or legal conclusions clearly exceeds the scope of what is permitted by the rule.

has a fiduciary duty to its shareholders to maintain its SOPs as a non-public, confidential document” (*id.*); (iii) “to release the proprietary documents would not only likely damage the company, and thus, its shareholders, but would also potentially run afoul of SEC regulations” (*id.* at 2-3); (iv) “[t]he plaintiffs’ request for Psychomedics’ SOP’s is also overly broad and is not relevant” (*id.*); (v) “production of Psychomedics SOP’s prior to 2002 is simply not relevant to the present action,” (*id.*); and (vi) “compliance with the subpoena places an undue burden on Psychomedics and the potential harm caused by production outweighs the benefit to the plaintiffs” (*Id.* at 4). These are conclusions of law that are superfluous, and that concern the very issues of law to be decided by the Court. These statements are wholly improper and should be stricken or disregarded. Witnesses—including experts—may not invade the court’s province by testifying on issues of law. *See In re Initial Pub. Offering Sec. Litig.*, 174 F.Supp.2d 61, 64 (S.D.N.Y. 2001). The judge’s “expert knowledge of the law makes any such assistance at best cumulative, and at worst prejudicial.” *Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92, 100 (1st Cir.1997). *Every circuit* has explicitly held that it is the responsibility of the court, and not of witnesses, to reach legal conclusions. *In re Initial Pub. Offering Sec. Litig.*, 174 F.Supp.2d at 64 (collecting authorities so holding). The legal conclusions proffered by Mr. Thistle in his affidavit should therefore be rejected, and stricken from the record or entirely disregarded.

II. THE COURT SHOULD STRIKE THE THISTLE AFFIDAVIT BECAUSE IT IS NOT BASED ON PERSONAL KNOWLEDGE.

Facts within the personal knowledge of the affiant are the only proper subject of affidavit testimony. 2A C.J.S. *Affidavits* § 45 (2007) (“it is an affiant’s personal knowledge, and his or her beliefs, opinions, rumors or speculation, that are the proper subject of any affidavit”); *see also, e.g., Garside v. Osco Drug, Inc.*, 895 F.2d 46, 49 (1st Cir. 1990) (stating that affidavit must be based on personal knowledge); *Richardson v. Oldham*, 12 F.3d 1373, 1378 (5th Cir. 1994) (finding that court properly struck one portion of affidavit as not based on personal knowledge and another portion on basis that it asserted legal conclusion); *Friedel v. City of Madison*, 832 F.2d 965, 969-70 (7th Cir. 1987) (holding that court properly ignored affidavit of plaintiff’s

attorney that contained claims that attorney believed to be true but that were not based upon personal knowledge); *Carnrite v. Granada Hosp. Group, Inc.*, 175 F.R.D. 439, 448-49 (W.D.N.Y. 1997) (striking affidavit of plaintiff's counsel because affidavit discussed facts not within counsel's personal knowledge). To the extent that Mr. Thistle lacks personal knowledge required to provide competent testimony, the Court should strike or disregard his affidavit for this additional and independently sufficient reason.

An affidavit which does not positively and unqualifiedly represent the facts as disclosed in the affidavit to be true and within the affiant's personal knowledge is legally insufficient. *See, e.g.*, 2A C.J.S. *Affidavits* § 45 (2007); *Galindo v. Dean*, 69 S.W.3d 623 (Tex. App. 2002). Mr. Thistle has not averred that *any* of the factual assertions made in his affidavit are based upon his personal knowledge. Although a court may infer personal knowledge from an affidavit itself, it need not do so when other evidence indicates that the affiant has no personal connection to the subject matter or there is other evidence suggesting that he or she did not, or could not, have personal knowledge of it. *See, e.g.*, 2A C.J.S. *Affidavits* § 45 (2007); *Lupo v. Wyeth-Ayerst Laboratories*, 4 F.Supp.2d 642, 649 (E.D. Tex. 1997); *United States v. Davis*, 792 F.2d 1299, 1304 (5th Cir.1986). It is highly doubtful that Mr. Thistle could have personal knowledge of all of the factual statements contained in his affidavit.

For example, Mr. Thistle is an attorney, yet he makes claims that imply an intimate knowledge of the business practices of drug testing laboratories generally. He states: "Testing laboratories do not, in the normal course of business, make available to the public their standard operating procedures, (SOPs), which are blueprints for their businesses." Thistle Affidavit at 1. Mr. Thistle does not even assert, let alone explain how, this information concerning industry-wide practices falls within his sphere of personal knowledge.

Mr. Thistle also lacks the requisite personal knowledge concerning his numerous statements of legal conclusion, discussed *supra*, for the simple reason that such legal prognostications could not possibly be the subject of his personal knowledge. For example, this Court has not yet ruled upon the question whether Plaintiffs' document subpoena is unduly

burdensome to Psychomedics. Therefore, it cannot conceivably be within Mr. Thistle's personal knowledge that the subpoena is unduly burdensome. Like the rest of his conclusory legal assertions, Mr. Thistle's claim to that effect must be stricken for the independent and sufficient reason that it is beyond the scope of his personal knowledge.

III. THE COURT SHOULD STRIKE THE THISTLE AFFIDAVIT BECAUSE IT PRESENTS IMPERTINENT, IMMATERIAL, CONTRADICTORY, AND MISLEADING STATEMENTS.

Fed. Rule Civ. P. 12(f) dictates that this Court may order stricken from any pleading "any redundant, immaterial, impertinent or scandalous matter." In addition to being shot through with statements that are inadmissible because they concern legal conclusions or are not within the knowledge of the affiant, the Thistle Affidavit contains multiple passages that are utterly beside the point of the Motion to which Psychomedics is ostensibly responding. Some portions of the affidavit are even internally inconsistent and misleading.

A. The Thistle Affidavit Should be Stricken From The Record Because it is Based on a Misleading, Illogical, and Self-Serving Assumption That Plaintiffs Have Retained Experts Employed by a Hair Testing Company.

Mr. Thistle signed an affidavit under oath that implies that Plaintiffs have retained experts employed by a competing hair testing company. Indeed, Psychomedics's opposition to the Motion relies entirely on cases concerning a *competitor's* efforts to obtain proprietary information. As Mr. Thistle states: "Production of the SOP's, even under a Protective Order, will provide opposing experts with the necessary data necessary [sic] not only to run a hair testing lab, but also to run a hair testing lab employing special test conditions, methods and equipment setting which have been optimized as a result of twenty plus years of running the Psychomedics laboratory." Thistle Affidavit at 1.

This argument—and it clearly is *an argument* and not a factual statement based on personal knowledge—is a *non sequitur*. The Plaintiffs are attacking the validity of the Hair Test. As Plaintiffs argued in their Motion, hair testing is unreliable and scientifically flawed, *inter alia*,

because it does not exclude external contamination of hair samples as the reason for a positive result on the Hair Test. Plaintiffs also maintain that this flaw has a disparate impact on officers and applicants of color. Not surprisingly, then, Plaintiffs have retained scientific experts to test the reliability of the Hair Test. These experts do not work for, have never have worked for, and have no intention of ever working for any company engaged in hair testing. Furthermore, Psychemedics has already been assured that any documents produced by Psychemedics in response to Plaintiffs' subpoena would be subject to the protections of the Order Governing The Production And Exchange of Confidential Information (the "Confidentiality Order") that is already in effect in this litigation. So, even if Plaintiffs' experts were affiliated with other hair testing companies, which they are not, the Confidentiality Order would prohibit Plaintiffs and their experts from using the SOPs for purposes outside this litigation.

B. The Thistle Affidavit Should be Stricken From The Record Because it is Internally Inconsistent.

This Court should not credit the contradictory statements in the Thistle Affidavit. For example, the only documents Plaintiffs have so far moved to compel are Psychemedics's SOPs, and Mr. Thistle avers that not even the Boston Police Department has access to the SOPs. Thistle Affidavit at 1. Yet, Mr. Thistle later asserts that "Plaintiffs, of course, already have access to publicly available documents that they claim contain the SOP information." Thistle Affidavit at 2. He also states that "[i]f the parties seek to know what the requirements are to conduct an accurate test employing Psychemedics' test methods, the data packages already provided to Boston PD contains [sic] this information." *Id.*

Mr. Thistle's assertions that Plaintiffs and defendants already have the information that Plaintiffs have moved to compel contradicts his other assertions and, moreover, misrepresents the Plaintiffs' position. The Plaintiffs have never contended that all the relevant information in the SOPs is publicly available. If that were the case, Plaintiffs would not have bothered with either the subpoena or the Motion in the first place.

Moreover, the prosecution of Plaintiffs' case requires several specific types of information that are likely to be found *only* in the SOPs. According to its published procedures and 510(k) summary, Psychemedics uses a particular assay (*i.e.* a test or analysis) known as Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) to determine the value of a drug in hair after its "washing procedure." Psychemedics then compares this value to the concentration of the drug in the last phosphate wash of its "wash procedure," which, unlike the LC/MS/MS assay used on the hair, is measured by radioimmunoassay (or "RIA," a laboratory technique that makes use of the binding between an antigen and its homologous antibody in order to identify and quantify the specific antigen or antibody in a sample). LC/MS/MS actually detects the amount of cocaine in the hair, whereas RIA detects cocaine-like materials in the final wash (comparing an RIA value with a LC/MS/MS value is the scientific equivalent of subtracting an apple from an orange, but, upon information and belief, Plaintiffs maintain that Psychemedics uses this comparison because it is cheaper, and, therefore, more profitable for Psychemedics). Depending on the cross-reactivity of the immunoassay in the RIA procedure, the RIA may report higher or lower levels of cocaine. In its 510(k) clearance materials, Psychemedics did provide cross-reactivity data for an immunoassay, but the cross-reactivity of the immunoassay in Psychemedics' current Hair Test is not publicly available anywhere. Without the exact immunoassay it is impossible to reproduce the Hair Test to assess its reliability.

Similarly, Psychemedics has published the fact that it multiplies the RIA value from its last wash by five and then subtracts that result from the LC/MS/MS value. If the result for cocaine is over 5ng/10mg, then Psychemedics reports the test as positive. There are several problematic, unknown variables in this calculation. For example, because the RIA value from the last wash is multiplied by five, an individual who is reported as positive but just over 5ng/10mg cutoff might have been considered negative if Psychemedics' RIA was able to detect a more trace value of cocaine in the final wash. Therefore, it is crucial to know what Psychemedics does when it detects a very low RIA value, and, more importantly, what the limit

of detection is for Psychomedics' RIA test, how that limit is determined, and what cocaine-like substances the RIA detects. There are similar unknowns regarding the detection limits and other criteria that Psychomedics applies for the LC/MS/MS test.

In sum, Mr. Thistle cannot have it both ways. Either the SOPs are publicly available, in which case Psychomedics cannot object to producing them on confidentiality grounds, or they are not publicly available, in which case Psychomedics cannot object to producing them on grounds that the Plaintiffs already have access to the information that they require. Psychomedics would simply prefer that the world accept the reliability of the Hair Test based solely on the incomplete data and information presented in its published scientific studies. However, to be reliable, a scientific procedure must be capable of repetition and review by other scientists. Without the SOPs, such repetition and review is impossible.

Another self-contradiction arises in connection with Mr. Thistle's statement that the SOPs present Psychomedics's "patented methodology." Thistle Affidavit at 1. Mr. Thistle makes yet another of his many straw man arguments that the SOPs will "provide opposing experts with the necessary data necessary [sic] not only to run a hair testing lab, but also to run a hair testing lab employing special test conditions, methods and equipment settings which have been optimized as a result of twenty plus years of running the Psychomedics laboratory." *Id.* If Psychomedics's SOPs reveal its "patented methodology," then Mr. Thistle's concern that another hair testing laboratory will simply copy that patented methodology for its own commercial use is a red herring; it would be plainly unlawful to duplicate a patented methodology.

C. The Thistle Affidavit Should be Stricken From The Record Because it Presents Several Immaterial And Irrelevant Factual Assertions.

The Thistle Affidavit is replete with immaterial and irrelevant assertions. First, Mr. Thistle argues that he "would be remiss in [his] duty as General Counsel of Psychomedics to advise the company to produce information of this kind" because to do so would "potentially run afoul of SEC regulations." Thistle Affidavit at 3. Mr. Thistle apparently advised Psychomedics not to produce the SOPs long before Plaintiffs filed the Motion, and it is simply irrelevant to the

resolution of the Motion whether Mr. Thistle gave the proper legal advice to Psychemedics or not. Furthermore, there is certainly no SEC regulation that would prohibit the Court from granting Plaintiffs all of the relief they have requested. If there were such a regulation, Mr. Thistle no doubt would have cited to it in his four-page legal opinion. This Court should credit neither Mr. Thistle's vague, speculative reference to unspecified "SEC regulations" nor his completely irrelevant mention of legal advice that he has or has not provided to his client.

Next, the Thistle Affidavit proceeds to tout the various licenses that Psychemedics has obtained "to conduct forensic toxicology drug testing." *Id.* at 3. These claims are immaterial, impertinent to the instant motion and seriously misleading. Boston Police Department Rule 111, Part D requires that the laboratory that defendants use to perform the Hair Test "shall be" "certified to perform hair testing." None of the licenses cited in the Thistle Affidavit are a certification to perform hair testing.³ Neither is the 510(k) marketing clearance that Psychemedics applied for and obtained from the Food and Drug Administration (the "FDA") such a certification. The 510(k) clearance process does not involve independent testing by the FDA, and 510(k) clearance is not the equivalent of official approval or certification of a device. In fact, it would be illegal to claim that a 510(k) cleared hair drug test was officially certified. *See* CFR Title 21, Part 807.39 ("Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.").

Finally, Mr. Thistle states that various licensing agencies have the authority to review Psychemedics's SOPs "to ensure the laboratory is also in compliance with its own established procedures." Thistle Affidavit at 3. These assertions do not support any of the reasons why

³ For instance, the first license attached to the Thistle Affidavit is Psychemedics's current license from The College of American Pathologists. This license states that Psychemedics is an Accredited Laboratory that "has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists' Forensic **Urine** Drug Testing Accreditation Program." (emphasis added).

Psychemedics has objected to producing its SOPs. To the extent it is relevant whether various licensing agencies have endorsed the reliability of the Hair Test or Psychemedics SOPs, Mr. Thistle does not go so far as to say that any of these agencies have ever made such an endorsement, much less that any of these licensing agencies have ever bothered to exercise their purported authority to evaluate the reliability and validity of Psychemedics's SOPs. Furthermore, the fact that various licensing agencies purportedly have the power to evaluate Psychemedics's SOPs belies Psychemedics's position that the company would be damaged if the SOPs were to be reviewed for their reliability by outside experts subject to tight confidentiality restraints.

The SOPs are subject to review by licensing agencies because the publicly available information concerning Psychemedics's hair testing procedures is insufficient to test the reliability of those procedures. The reliability of the Hair Test is indisputably of central concern in this action, and Psychemedics has provided no reason why the ability of the Plaintiffs and this Court to evaluate Psychemedics's procedures should be inferior to that of the licensing agencies. The Thistle Affidavit should be stricken or disregarded, and the SOPs produced.

CONCLUSION

For all the foregoing reasons, this Court should grant the Plaintiffs' Motion and enter an Order striking the Thistle Affidavit in its entirety, or disregarding the Thistle Affidavit and striking all references to it in the Opposition. Further, Psychemedics should be ordered to pay the Plaintiffs' costs, including attorneys' fees, incurred in bringing this Motion, in an amount to be determined upon submission of an affidavit setting forth such costs.

Respectfully submitted,

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Dated June 15, 2007

CERTIFICATE OF SERVICE

I hereby certify that, on June 15, 2007, a true copy of the above document was served upon the attorney of record for each other party and counsel for Psychemedics, J. Allen Holland, Jr., electronically via the ECF/CM.

/s/ Robert B. Baker